

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Michael Austin, Don Robinson, Dennis R. Boulais, Praveen Kulkarni, Toby Freyman, Samuel J. Epstein, Wendy Naimark, Marlene Schwarz
Application No.:	10/797704
Filed:	March 9, 2004
For:	Coated Medical Device and Method for Manufacturing the Same
Examiner:	Laura Estelle Edwards
Group Art Unit:	3738

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P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-14067-US01

REPLY BRIEF

This is a Reply Brief for the above-identified Application, in response to the Examiner's Answer mailed July 19, 2010.

Status of the Claims

Claims 17, 19-29 and 36-39 are pending in the application. Claims 1-16, 18 and 30-35 were previously canceled. Claims 17, 19-29 and 36-39 have been finally rejected and are the subject of this appeal.

Grounds of Rejection to be Reviewed on Appeal

Issue 1: Whether US 6111345 is a translation of JP 11-111423.

Issue 2: Whether the Examiner erred in rejecting claims 21-26 and 36-38 under 35 USC § 103 over Pacetti (US 2005/0074544) in view of Shibata (JP 11-111423), and in rejecting claims 27-29 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Kirk Othmer (Encyclopedia of Chemical Technology).

Issue 3: Whether the Examiner erred in rejecting claims 17 and 20 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Pacetti '874 (US 7175874).

Issue 4: Whether the Examiner erred in rejecting claim 19 under 35 USC § 103 over Pacetti in view of Shibata and Pacetti '874 and further in view of Layrolle (US 2001/0008649).

Issue 5: Whether the Examiner erred in rejecting claim 39 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Pomper (US 2842092).

Argument

This Reply Brief supplements the Appeal Brief submitted June 1, 2010. Remarks are grouped according to the classification of Issues used in the Appeal Brief.

Issue 1: Whether US 6111345 is a translation of JP 11-111423 (Shibata).

Applicants previously asserted that US 6111345 should not be considered an a translation of Shibata because the ‘345 patent clearly includes subject matter that goes beyond the scope of Shibata, and because it has not been shown that the ‘345 patent includes a translation of the entire text of Shibata. See Appeal Brief at page 7.

In response, the Examiner has asserted that the ‘345 patent is a translation because it was provided to the Examiner by the Scientific and Technical Information Center (STIC). See Examiner’s Answer at page 2. This does not meet the requirements of the MPEP to show the contents of Shibata.

The Examiner’s conclusory assertion is not sufficient to establish that the ‘345 patent is a true translation of Shibata. The Examiner has not cited to any authority that supports the assertion that a document is legally viewed as a true translation merely because it has been provided to an Examiner by the STIC.

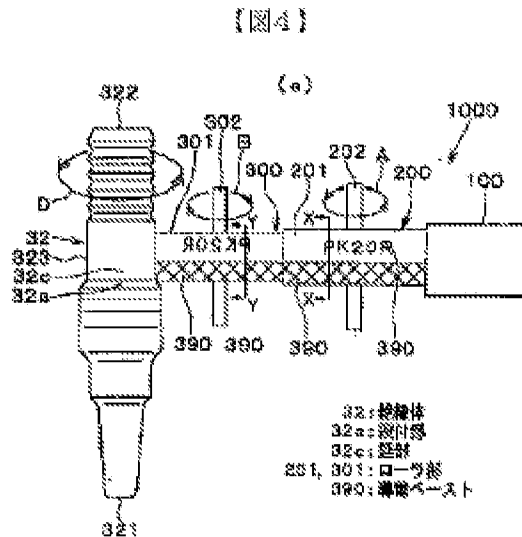
Therefore, Applicants assert that the Examiner has not provided a translation of Shibata as required by MPEP § 706.02 II, which states, “If the document is in a language other than English and the examiner seeks to rely on that document, a translation must be obtained so that the record is clear as to the precise facts the examiner is relying upon in support of the rejection.” The MPEP notes that a translation is important because, in some instances, “the full text document will include teachings away from the invention that will preclude an obviousness rejection under 35 U.S.C. 103, when the abstract alone appears to support the rejection.” MPEP § 706.02 II.

The ‘345 patent should not be considered an accurate translation of Shibata merely because some level of relationship can be found through an obscure chain of priority. Although the ‘345 patent claims priority to seven Japanese references, it does not claim priority to Shibata JP 11-111423. On the record in this case it still has not been shown that the ‘345 patent includes a translation of the entire content of Shibata in compliance with MPEP§706.02 II.

Issue 2: Whether the Examiner erred in rejecting claims 21-26 and 36-38 under 35 USC § 103 over Pacetti (US 2005/0074544) in view of Shibata (JP 11-111423), and in rejecting claims 27-29 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Kirk Othmer (Encyclopedia of Chemical Technology).

The Examiner argues that Shibata teaches an indirect coating arrangement, and that modifying Pacetti's direct coating arrangement to include a second roller as taught by Shibata would improve the Pacetti device. In particular, the Examiner asserts that a second roller will "allow for a more metered supply of coating material onto the surface of the stent thereby enhancing uniformity." See Examiner's Answer at page 5.

Shibata does not support the Examiner's broad assertion that a second roller of an indirect system generally can be expected to provide better metering over a single roller coating system. Shibata discloses a specialized coating system that applies coating material in particular shapes and arrangements, such as in the shapes of letters. See e.g. Shibata Figure 4a, provided below.

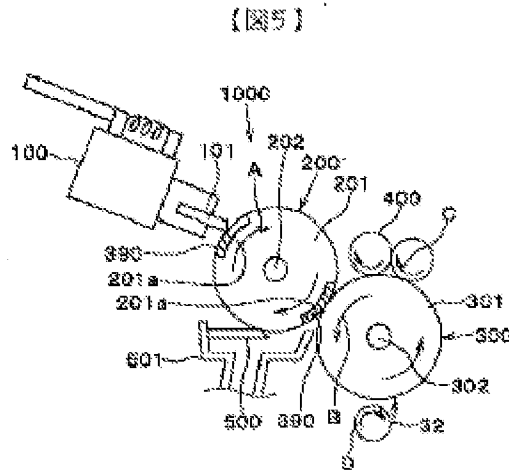


Shibata Fig. 4a

The Examiner has not cited to any teaching from Shibata that establishes that the second roller 301 performs a metering function. The Examiner has only referred to an ambiguous drawing and speculated as to the metering function. There is nothing in the record showing the second roller achieves any metering.

As shown in Shibata Figure 5, provided below, coating material 390 is placed into

cavities in the first roller 201 by a dispensing system 101. From Figure 5, it appears that the dispensing system 101 performs the metering by dispensing coating material 390 only into the cavities. The second roller 301 appears only to transfer the coating material 390 from the cavities in the first roller 201 to the insulator 32 of the spark plug. See also English Abstract of Shibata.



Shibata Fig. 5

Thus, it has not been shown that the second roller 301 in the Shibata system provides any metering. The Examiner has not established that a person of ordinary skill in the art would have recognized a metering function in the second roller of Shibata.

Further, even if Shibata's second roller does perform some level of benefit when used in the marking/transfer roller system taught by Shibata, the Examiner has not established that a similar benefit would be achieved if Shibata's second roller were used in the Pacetti device. For example, the '345 patent teaches that the first roller is an inelastic intaglio roller and the second roller is a rubber transfer roller. See column 20, lines 58-66. The Examiner has not established that an elastic roller would be expected to have similar benefit in the hypothetically modified Pacetti device, because that device does not have an intaglio roller.

The Examiner's assertion that the rejection does not propose to use Shibata's particular roller, but instead the generic concept of a second roller, amounts to a broadening of Shibata using impermissible hindsight. The cited documents do not provide such a generalized teaching.

The Examiner provides reasoning to support the rejection in the Examiner's Answer at page 11; however, these assertions are not supported by the applied references. For example, in asserting that additional rollers provide for a better coating, the Examiner states:

The continued transfer of coating material from roller to roller smooths or levels the coating material and actually to some extent lessens the amount of coating eventually applied to the object or article or substrate. This aforementioned arrangement defines an indirect roller coating arrangement wherein a metered or controlled amount is applied more uniformly because excess lumps, air bubbles, etc., have been removed via the transference of coating material from roller to roller eventually to arrive at the object or article or substrate being coated.

The above assertions are not supported by Shibata. Further, a person of ordinary skill in the art will recognize that the addition of rollers does not necessarily result in a better coating. Under the Examiner's contention, a system having three rollers should perform better than a system having two rollers; a system having four rollers should perform better than a system having three rollers, etc. However, it is also possible that such additional rollers might result in a decrease in coating uniformity, introduction of air bubbles, etc.

The above-copied paragraph from the Examiner's Answer concludes with the following sentence:

This indirect roller coating arrangement is conventional wisdom to the routineer in the coating art.

The Examiner's conclusion is not supported by the Shibata reference. If such knowledge amounts to conventional wisdom of the routineer, the Examiner should be able to support the assertion with more evidence than a drawing from Shibata, which is ambiguous as to the general benefits of an indirect roll coating arrangement.

Shibata does not support the Examiner's broad assertions or the reasoning necessary to maintain the rejection. Since the Examiner's reasoning is not supported by the applied references, the Examiner's assertions amount to an impermissible hindsight use of Applicant's disclosure.

A person of ordinary skill in the art, viewing Pacetti and Shibata without an artificial goal of reaching the pending claims, would not have been motivated to modify Pacetti using Shibata's second roller. Applicants request that the Board reverse all of the Examiner's

rejections that apply Pacetti in view of Shibata.

Dependent Claims 21 and 23

The Examiner asserts that “Shibata provides the surface of the second roller (301) being grooved as illustrated in Fig. 4a/b.” See Examiner’s Answer at page 5.

Shibata does not show grooves in the second roller. Shibata Figures 4b, 4c and 5 are provided below. From Figures 4b and 5, it is understood that the first roller 201 includes cavities, and that the Figures depict conductive paste 390 oriented in the cavities.

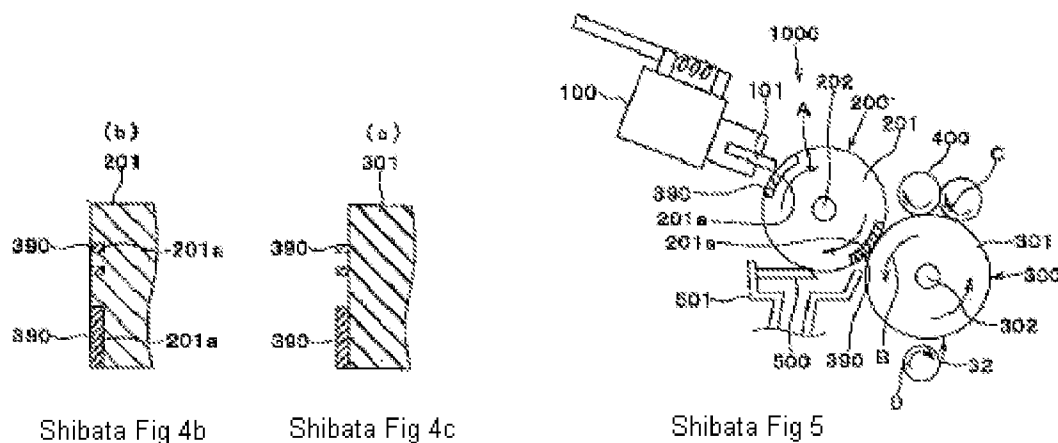


Figure 4c, as understood, shows the second roller 301 having conductive paste 390 on the roller surface. From Figures 4c and 5, it is understood that the surface of the second roller 301 is smooth. It appears that the Examiner erroneously interpreted the paste 390 in Figure 4c to be protrusions in the roller surface.

The limitations of claims 21 and 23 have not been shown, and the Examiner has not presented a *prima facie* case of unpatentability against these claims. Applicants request that the Board reverse the rejection of claims 21 and 23.

Issue 3: Whether the Examiner erred in rejecting claims 17 and 20 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Pacetti ‘874 (US 7175874).



Applicants stand on the previous arguments with respect to claim 17; however, Applicants further traverse the Examiner’s construction of “circulate,” as recited in claim 20.

The Examiner argues that the definition of circulate provided by Applicants is

inconclusive as to one-way vs. two-way flow. The Examiner asserts that “circulate” applies to one-way flow and “recirculate” would apply to two way flow. See Examiner’s Answer at page 15. This is an unreasonable contention on the record in this case.

The word “recirculate” does not generally have a separate definition from the term “circulate.” For example, if the term “recirculate” is entered at Dictionary.com, the result redirects to “circulate.” See “recirculate.” Dictionary.com. Dictionary.com Unabridged. Random House, Inc. <http://dictionary.reference.com/browse/recirculate> (accessed: September 15, 2010).

recirculate - 4 dictionary results

cir·cu·late  [sur-kyuh-leyt]  [Show IPA](#) **verb**, -lat-ed, -lat-ing.

–verb (used without object)

1. to move in a circle or circuit; move or pass through a circuit back to the starting point: *Blood circulates throughout the body.*

Applicants note that the definition of “recirculate” above provided 4 dictionary results, including a Medical Dictionary result and a Science Dictionary result. Both the Medical and Science Dictionary definitions support Applicant’s interpretation of “circulate” and are contrary to the Examiner’s contention. These results are shown below.

Medical Dictionary

cir·cu·late definition

Pronunciation: /ˈsər-kyə-ˌlāt/


Function: vi

-lat·ed ; , -lat·ing ; : to flow or be propelled naturally through a closed system of channels (as blood vessels) *circulate s* through the body>

Merriam-Webster's Medical Dictionary, © 2007 Merriam-Webster, Inc.

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Science Dictionary

circulate  (sûr'kyə-lăt') Pronunciation Key

To move in or flow through a circle or a circuit. Blood circulates through the body as it flows out from the heart to the tissues and back again.

This American Heritage® Science Dictionary

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In the term “recirculate,” the “re” is merely a prefix that means “again.” Thus, “recirculate” would mean to circulate again, not to have some different path of circulation.

A person of ordinary skill in the art would recognize that the circulation between the reservoir and the source recited in claim 20 helps to achieve a more uniform supply of coating material. The application teaches that the reservoir can be a fermentor containing cells. See paragraph 0061. A person of ordinary skill in the art would recognize that in coatings containing items of variable concentration (e.g. cells, which may be growing and/or reproducing), circulation between the source and reservoir, as defined by Applicants, helps to ensure a uniform concentration of the items/cells.

Further, claim differentiation suggests that Applicant’s asserted construction of “circulate” is appropriate. Claim 17 recites a “reservoir that continuously supplies the coating material source.” Thus, the device of claim 17 will exhibit at least one-way flow from the reservoir to the source. Claim 20 depends from claim 17, and further limits claim 17. If claim 20 is interpreted in accordance with the Examiner’s assertion, claim 20 will have no meaning. When claim 17 is considered, the only reasonable interpretation of “circulate” in claim 20 is the interpretation asserted by Applicants.

The applied references do not disclose or suggest the circulation required by claim 20, and a *prima facie* case of unpatentability has not been presented.

Issue 4: Whether the Examiner erred in rejecting claim 19 under 35 USC § 103 over Pacetti in view of Shibata and Pacetti ‘874 and further in view of Layrolle (US 2001/0008649).

In the previously filed Appeal Brief, Applicants essentially argued that the submersion/precipitation coating method disclosed by Layrolle is not compatible with the roller

coating system of Pacetti/Shibata.

In response, the Examiner asserts that “use of a fermentor with cells as taught by Layrolle as a form of an active biological supply to the indirect roller applicator apparatus as defined by the combination above would be well within the purview of one skilled in the art.” See Examiner’s Answer at page 16.

The Examiner’s assertion that Layrolle teaches a “fermentor with cells,” as recited in claim 19, is traversed as unequivocally incorrect.

The Examiner cites to Layrolle paragraph 0037. See Examiner’s Answer at page 8. Although the cited paragraph does mention a “fermentor system” or a “bioreactor system for culturing cells,” Layrolle does not actually use any cells in the fermentor/bioreactor. The disclosure is simply that a particular type of vessel can be used. Layrolle does not use cells as a coating.

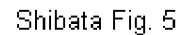
The carbonated calcium phosphate film coatings disclosed by Layrolle are not cell coatings and do not contain cells. The calcium phosphates are the principal constituent of bone. See e.g. paragraphs 0001-0003. The bulk of the Layrolle disclosure appears to discuss forming mineral film coatings on stents via ordinary chemical reactions. See e.g. paragraph 0042 and equations (1)-(3). No biology takes place in the vessel.

Layrolle does not disclose or suggest cells as a coating. Layrolle does not disclose or suggest growing cells or reproduction of cells. Paragraph 0037 appears to state that existing fermentor or bioreactor systems, which are generally suitable for culturing cells, can be used to crystallize the calcium phosphate film coatings discussed in the Layrolle reference. Thus, Layrolle does not actually disclose or suggest any use of cells, or use of a fermentor that actually contains cells.

Therefore, Applicants assert that the applied references do not disclose or suggest each limitation of claim 19. The teachings of Layrolle would not motivate a person of skill in the art to add cells as required by claim 19, and a *prima facie* case of unpatentability has not been presented. Applicants request that the Board reverse the rejection of claim 19.

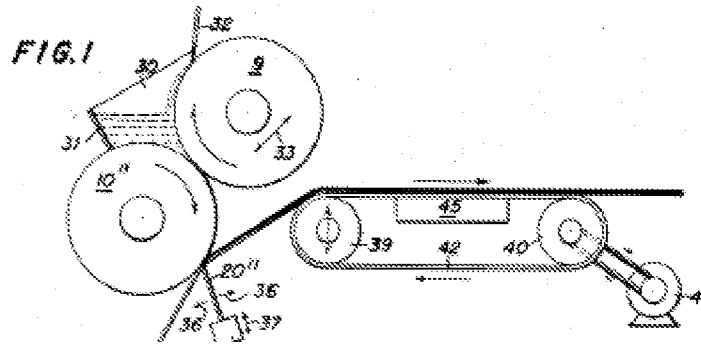
Issue 5: Whether the Examiner erred in rejecting claim 39 under 35 USC § 103 over Pacetti in view of Shibata and further in view of Pomper (US 2842092).

As illustrated in Shibata Figure 5, provided below, the transfer roller 301 must contact the shaped roller 201 in order to transfer the coating. If the transfer roller 301 were adjusted to create a gap between the shaped roller 201 and the transfer roller 301, the coating material would not be transferred.



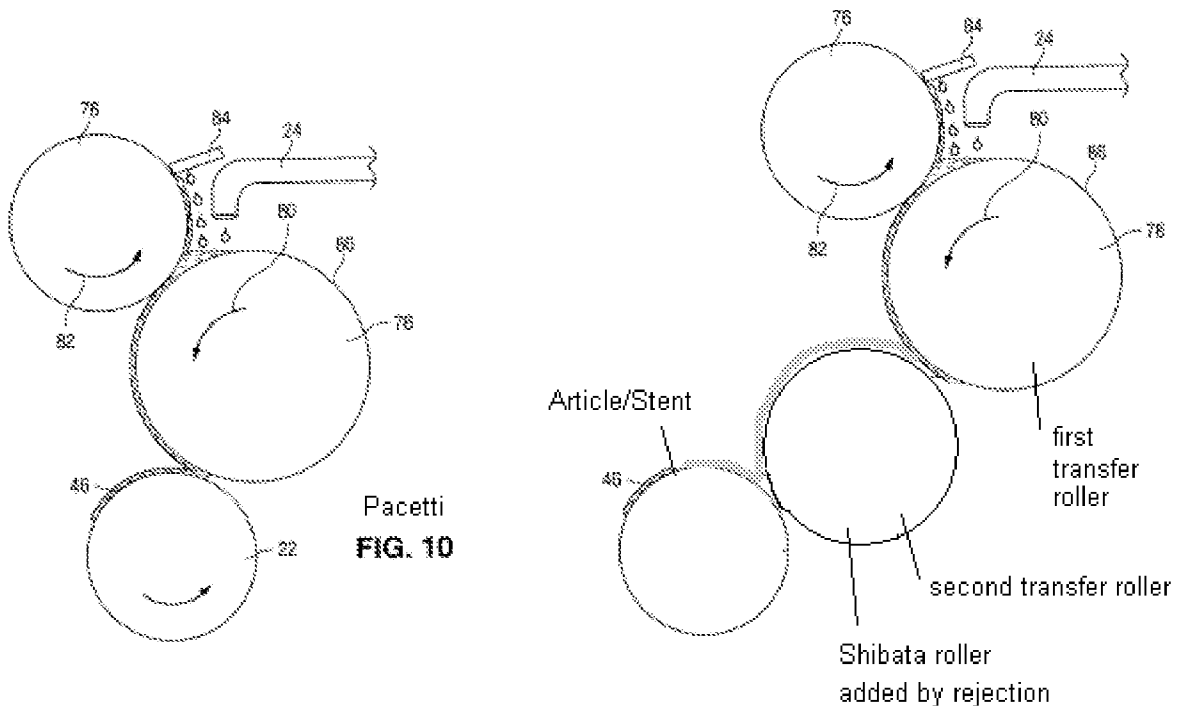
Further, if a metering function as disclosed by Pomper were desired in the Pacetti/Shibata device proposed by the Examiner, it is unclear why the adjustability would be incorporated between the two transfer rollers, when the teachings of Pomper would suggest to incorporate the adjustability between Pacetti's metering roller and application/first transfer roller.

Pomper provides a transfer roller 10" and a metering roller 9 arranged to rotate in opposite directions. The distance adjustability 33 of the metering roller 9 provides for metering of the coating. See Figure 1, provided below, and column 3, lines 46-51.



Pomper's metering system relies upon a reservoir created by dams 30, 31, 32. As illustrated in Figure 1, the reservoir is capable of supplying a greater amount of coating material than the amount of coating material that can pass between the rollers 9, 10".

Pacetti discloses a similar system having a metering roller 76 and an application/transfer roller 78 arranged to rotate in opposite directions. As illustrated in Figure 10, the feeder 24 appears to supply more coating material than can pass between the rollers 76, 78 in a gravity-fed arrangement. See Figure 10, provided below left, and paragraph 0049.



Applicants have provided a modified version of Pacetti Figure 10, above right, which shows a Shibata roller as proposed by the Examiner added to the Pacetti device.

The teachings of Pomper might arguably suggest adding distance adjustability between Pacetti's metering roller 76 and application/transfer roller 78, as these rollers are analogous to the Pomper rollers. Pomper provides no suggestion to provide distance adjustability between two transfer rollers (e.g. Pacetti's original application/transfer roller 78 and the Shibata roller).

The applied references do not disclose or suggest metering by adjustability between two transfer rollers, wherein the first transfer roller receives a supply of coating material that has already been metered. The Examiner's proposal to add such adjustability amounts to an impermissible hindsight use of Applicants' teachings in an attempt to reach the pending claims without rational support in the cited documents.

Therefore, a *prima facie* case of unpatentability has not been presented against claim 39. Applicants request that the Board reverse the rejection of claim 39.

Argument Conclusion

Based on at least the arguments presented in the Appeal Brief filed June 1, 2010 and the supplemental arguments presented herein, Applicants respectfully assert that the rejections presented by the Examiner fail to establish a *prima facie* case of obviousness against any of the pending claims. Accordingly, Applicants respectfully request that the Board reverse all of the rejections asserted by the Examiner.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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Claims Appendix

17. The system of claim 22, which further comprises a reservoir that continuously supplies the coating material source with coating material.

19. The system of claim 17, wherein the reservoir is a fermentor containing cells.

20. The system of claim 17, wherein the coating material is circulated between the reservoir and the coating material source.

21. The system of claim 22 wherein the surface of the second roller comprises a plurality of grooves.

22. A system for coating a stent having a tubular portion with an outer surface, wherein the system comprises:

a coating material source containing a coating material comprising a solvent and a biologically active material;

a first roller having a surface;

a doctor blade in proximity to the first roller surface positioned to remove excess coating material from the first roller surface; and

a second roller having a surface, wherein:

the first roller is situated relative to the coating material source so that the coating material in the coating material source is transferred to the first roller surface;

the first roller and second roller are situated relative to each other so that the first roller transfers the coating material transferred to the first roller surface to the second roller surface, and

the second roller is situated relative to the tubular portion so that the second roller transfers the coating material transferred to the second roller surface to the outer surface of the tubular portion.

23. The system of claim 22, wherein the surface of the second roller is rougher than the surface of the first roller.
24. The system of claim 22, wherein the surface of the first roller contacts the surface of the second roller and the surface of the second roller contacts the outer surface of the tubular portion.
25. The system of claim 22, further comprising a supplemental mechanism for removing excess coating material from the surface of the first roller.
26. The system of claim 25, wherein the supplemental mechanism is at least one of a metering roller or an air knife.
27. The system of claim 22, further comprising an energy source for converting the coating material applied to the outer surface of the tubular portion into a coating.
28. The system of claim 27, wherein the energy source is a heater.
29. The system of claim 27, wherein the energy source is an ultraviolet source.
36. The system of claim 22, wherein the biologically active material comprises a genetic material.
37. The system of claim 22, wherein the biologically active material comprises an antibiotic or an antiproliferative agent.
38. The system of claim 22, wherein said first roller surface comprises an outer surface.
39. The system of claim 22, wherein a distance between the first roller and the second roller is adjustable to control the thickness of the coating material.